COLLORA LLP

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September 30, 2013

VIA ELECTRONIC DELIVERY AND U.S. MAIL

Ms. Susan Liner
NWE-DO Recall Coordinator
U. S. Food and Drug Administration
One Montvale Avenue
Stoneham, MA 02180
Email: Susan.Liner@fda.hhs.gov

Re: Ameridose: Disposal of Non-Controlled Products

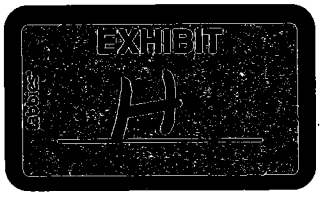
Dear Ms. Liner:

Thank you for continuing to work with Ameridose as it seeks to terminate its recall and to dispose and return product on-hand. In response to your emails on July 10 and July 16, I am writing to provide you with information regarding the disposal of "non-controlled" products. To be clear, "non-controlled" products refers to products that do not fall within the five Schedules used by the Drug Enforcement Administration ("DEA") and established by the federal Controlled Substances Act, 21 U.S.C. § 812.[1] At Ameridose, such non-controlled products are commonly referred to as "C-6" products.

With your approval, Ameridose intends to dispose of non-controlled products through RP Returns, a reverse distributor. A copy of the Statement of Work that RP Returns has provided to Ameridose detailing its disposal process is enclosed with this letter. Also enclosed with this letter is a spreadsheet entitled "C-6 Waste Inventory", which lists the non-controlled products that Ameridose intends to dispose of through RP Returns. The list is comprised of:

- Expired non-controlled products that were returned to Ameridose as part of the recall
- Expired non-controlled stock solutions (these are in-process solutions, some of which were never used and some which were partially used)
- Expired non-controlled bulk medication

[1] Under Massachusetts Department of Public Health regulations, prescription medications that are not included in any of the Schedules of the federal Controlled Substances Act are designated as "Schedule VI" products. *See* 105 CMR 700.002.



- Expired non-controlled products, some of which were never distributed, and some of which were partially distributed

- Expired non-controlled QA library samples

Once the FDA has approved of Ameridose's disposal process, Ameridose will set a date for RP Returns to come to Ameridose to pick up the materials described above and transport them to the incineration facility. It is my understanding that FDA may wish to observe some or all of this process. Please note that the proposal by RP Returns delineates that the pick-up and incineration process will take three days.

To be clear, to the extent that Ameridose has unused, unexpired bulk products it has been, and will continue to return those products. These returns have been on-going since January 2013, per my telephone and email exchange with Karen Archdeacon on January 2, 2013. If vendors do not accept these returns, Ameridose will also destroy of such items according to the process described above.

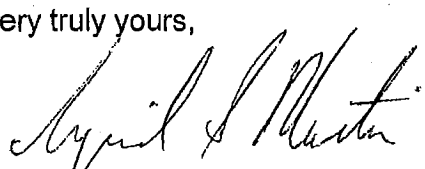
Finally, please be advised that Ameridose also intends to dispose of miscellaneous waste currently located at both the 201 and the 205 Flanders Road facilities. Specifically, this waste consists of:

- Seven 4' x 4' x 4' Gaylord Boxes at 205 Flanders Road Facility filled with assorted in-process non-control waste, expired/wasted diluent bags, expired/wasted devices, used tubing sets, empty vials, empty stock bags

- Five 4' x 4' x 4' Gaylord Boxes at the 201 Flanders Road Facility filled with assorted in-process non-control waste, expired/wasted diluent bags, expired/wasted devices, used tubing sets, empty vials, empty stock bags

Please let me know at your earliest convenience whether the plan set forth above is acceptable.

Very truly yours,



Ingrid S. Martin
Enclosure

cc: Nancy Dolberg, Massachusetts Department of Public Health (electronic delivery)
Nathaniel Yaeger, Chief of Health Care Fraud Unit, United States Attorney's Office (electronic delivery)